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October 17, 2024

The Honorable Gregory B. Williams
United States District Court
for the District of Delaware
J. Caleb Boggs Federal Building
844 North King Street
Wilmington, DE 19801

*VIA ELECTRONIC FILING
and HAND DELIVERY*

Re: *Array Biopharma Inc. v. Teva Pharmaceuticals, Inc.*
C.A. No. 23-625 (GBW)

Dear Judge Williams:

The parties to the above-referenced action jointly submit this joint letter regarding a proposed scheduling order for this case.

Pursuant to the Court's Order (D.I. 13) and the subsequent stipulation to extend time for the parties to submit a proposed scheduling order to October 17, 2024 (D.I. 14), Array hereby submits the attached proposed scheduling order for the Court's consideration. The parties disagree over whether this case should proceed in view of the Court's construction of the term "[c]rystallized 6-(4-bromo-2-fluorophenylamino)-7-fluoro-3-methyl-3H-benzoimidazole-5-carboxylic acid (2-hydroxyethoxy)-amide" (i.e. "crystallized [binimetinib]") recited in U.S. Patent Nos. 9,562,016; 9,598,376; and 9,980,944 (collectively, the "Crystallized Binimetinib Patents") in Array's related litigation against Alembic Pharmaceuticals Limited and Sandoz Inc. (C.A. No. 1:22-1277-(GBW), the "Alembic/Sandoz litigation"). *See* Alembic/Sandoz litigation, April 16, 2024 Order and Memorandum Opinion on claim construction, D.I. 93, 94. In this case, Array is asserting only the Crystallized Binimetinib Patents against defendant Teva Pharmaceuticals, Inc. ("Teva") in this case. Array acknowledges that Teva does not infringe the Crystallized Binimetinib Patents under the Court's claim construction in the Alembic/Sandoz litigation. Accordingly, Array is willing to agree to a modified schedule addressing the construction "crystallized [binimetinib]" prior to any discovery or contention-related deadlines. Alternatively, should the Court be inclined to stay this case per Teva's request below, Array respectfully requests that the Court issue the same construction of "crystallized [binimetinib]" from the Alembic/Sandoz litigation and enter judgment in this case so Array can appeal the construction to the Federal Circuit.

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Array's position: The Court's construction of "crystallized [binimetinib]" in the Alembic/Sandoz litigation does not preclude Array from asserting the Crystallized Binimetinib Patents against Teva. Claim constructions generally do not have preclusive effect because they are not final orders until the court enters final judgment. *See, e.g., RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1261 (Fed. Cir. 2003) (concluding that "collateral estoppel does not apply in the present case because no judgment, much less final judgment, was ever entered in the [earlier] Virginia district court case" where the parties settled after the court construed the claims but prior to entering a final judgment). Here, in the related Alembic/Sandoz litigation, "[t]he Parties agree[d] that neither Array nor [Alembic/Sandoz] seeks immediate entry of final judgment of invalidity or noninfringement under FRCP 54(b) and, instead, the Parties request that the stipulated order of invalidity and order of noninfringement be incorporated into any final judgment entered in this litigation" Alembic/Sandoz litigation, D.I. 133 at ¶5; D.I. 134 at ¶5. As a result, the Court's claim construction order in the Alembic/Sandoz litigation is not a final judgment and therefore does not preclude Array from revisiting the Court's claim construction of the crystallized binimetinib term in this case.

Array respectfully submits that in construing the crystallized binimetinib term, the Court improperly relied on incorrect facts presented by Alembic's counsel in the guise of "expert opinion," though neither Alembic nor Sandoz submitted an expert report during claim construction briefing or expert testimony at the Markman hearing. Accordingly, Array will ask the Court to reconsider the claim construction issue in this case.

Teva's position: Defendant Teva Pharmaceuticals, Inc. ("Teva") respectfully requests that this Court exercise its inherent power to stay the case pending resolution of any appeal of the Court's claim construction in the related litigation *Array BioPharma, Inc. v. Alembic Pharmaceuticals Ltd.*, No. 22-cv-1277-GBW (the "Alembic/Sandoz litigation").¹ Plaintiff Array Biopharma Inc. ("Array") asserts only three patents against Teva in this case—U.S. Patent Nos. 9,562,016, 9,598,376, and 9,980,944 (the "Crystallized Binimetinib Patents"). As Array expressly admits, however, "Teva does not infringe the Crystallized Binimetinib Patents under the Court's claim construction in the Alembic/Sandoz litigation." *See supra*. Thus, Array concedes that it currently has no basis to proceed against Teva. Array's only argument for moving forward in this case is that Array seeks a second bite at the apple—"revisiting the Court's claim construction of the crystallized binimetinib term in this case" and "ask[ing] the Court to reconsider the claim construction issue in this case." *Id.* But doing this in the context of the case against Teva is improper and inefficient. If Array wishes to re-litigate this Court's claim construction from the Alembic/Sandoz litigation, it can and should do so by appealing to the Federal Circuit. The Court should not entertain Array's attempt to re-litigate claim construction in this case and should instead enter a stay.

In determining whether to grant a stay, the Court considers "(1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party."

¹ If the Court would prefer that Teva file a formal motion for a stay, Teva is willing to do so as soon as possible.

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UCB, Inc. v. Zydus Pharms. (USA) Inc., No. CV 16-903-LPS, 2017 WL 4310860, at *1 (D. Del. Sept. 28, 2017). All three factors clearly favor entering a stay and denying Array a frivolous second bite at the apple.

Factor 1 favors a stay because the Court's current claim construction does not just simplify the issues, it resolves all the issues in this case and precludes a finding of liability against Teva, as Array has already admitted above. *See supra*; *see also Pers. Genomics Taiwan, Inc. v. Pac. Biosciences of California, Inc.*, No. CV 19-1810-GBW-MPT, 2022 WL 4245532, at *2 (D. Del. Sept. 15, 2022) ("Judicial efficiencies would be gained by staying this case rather than have this Court and the Federal Circuit address the construction of the same term in parallel.") (Williams, J.); *see also UCB*, 2017 WL 4310860, at *1 (first factor weighed in favor of a stay where validity of all claims in asserted patent would be decided in related appeal); *see also Choon's Design Inc. v. Tristar Prod., Inc.*, No. 14-10848, 2018 WL 11351661, at *2 (E.D. Mich. July 13, 2018) (stay pending appeal of claim construction decision in related action simplified infringement issue; stay granted). Accordingly, there would be no need for a trial, nor any other litigation, unless an appeal reverses this Court's already-entered claim construction. Additionally, Teva is willing to agree to be bound not just by this Court's claim construction already entered in the Alembic/Sandoz litigation, but also by the final resolution of the claim construction upon appeal.

As to factor 2, "[g]ranting a stay relatively early in a case can be said to advance judicial efficiency and maximize the likelihood that neither the Court nor the parties expend their assets addressing claims in the absence of liability." *454 Life Scis. Corp. v. Ion Torrent Sys., Inc.*, No. CV 15-595-LPS, 2016 WL 6594083, at *4 (D. Del. Nov. 7, 2016) (quotation marks and alterations omitted). Here, Array declined to take any steps to prosecute this action against Teva for more than twelve months. Aside from Teva reaching out to Array multiple times to propose settling the current action, the parties' only substantive exchange has been regarding the schedule for the case. Like the litigation stayed in *UCB*, although more than a year old, "this litigation is in its infancy." 2017 WL 4310860, at *2. Thus, a stay would not cause a waste of already-expended resources by the parties. Instead, a stay would prevent the parties from wasting resources by re-litigating an issue already decided by this Court.

Factor 3 also favors a stay because no prejudice, much less undue prejudice, would result for Array. Array has wholly failed to prosecute this action, and cannot complain that delay would work prejudice after allowing its suit to languish for a full year without attempting to achieve resolution. In the meantime, Array has had the full opportunity to litigate the relevant claim construction issue in the context of the Alembic/Sandoz litigation, and that claim construction resolves the issue of liability here, as Array admitted above. *See supra*. Moreover, Teva has not sought to bring its proposed ANDA product to market before the expiration of the Huang patents (U.S. Patent Nos. 9,314,464, 9,850,229, and 10,005,761), which is expected in or after the year 2030. Accordingly, a stay would not prejudice Array even if it had not slept on its rights. In the event the Federal Circuit overturns this Court's claim construction on appeal, Array could expect to fully litigate its case against Teva to completion before Teva seeks to launch its proposed product (or discuss a resolution in good faith with Teva).

Finally, the Court should reject Array's suggestion that it will appeal the claim construction from the Alembic/Sandoz litigation in the separate Teva case. Teva did not participate in the

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discovery, briefing, or argument concerning claim construction. Nor does the record in the Teva case contain the underlying materials that support the Court's claim construction. If Array believed an immediate appeal was appropriate, it should have sought that remedy in the Alembic/Sandoz litigation. The most efficient result would be to stay the Teva case and, at the appropriate time, allow the parties who briefed and argued the claim construction before this Court to address the matter on appeal.

For the reasons given above, Teva respectfully requests that the Court enter a scheduling order staying all discovery and administratively closing the case pending an appellate decision on the Court's claim construction order in the Alembic/Sandoz litigation.

Teva reserves the right to seek fees from Array should Array force Teva to relitigate the same claim construction issue already decided in the Alembic/Sandoz litigation.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

Attachment

cc: Clerk of the Court (via hand delivery; w/attachment)
All Counsel of Record (via electronic mail; w/attachment)